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Atty. Docket No.: P67397US0

**REMARKS**

The Office Action mailed June 6, 2005, has been carefully reviewed and Applicants note with appreciation the identification of allowed subject matter.

By this Amendment, Applicants have canceled claims 74-79, and amended claims 19, 54 and 60. Claims 1-27 and 29-73 are pending in the application. Claims 1 and 60 are independent. Claims 61, 65, 66 and 73 are withdrawn from further consideration.

As an initial matter, claims 1-59 are allowed. With the allowance of generic claim 1, claims dependent on claim 1 that were previously withdrawn have now been considered and allowed as claims to additional species that include all the limitations of the allowed generic claim. Within these previously withdrawn claims, informalities were noted in claims 19 and 54 which have been corrected herein.

Independent claim 74, and claims 75-79 dependent thereon, have been canceled as being directed to a non-elected species and to place the application into condition for allowance.

The remaining generic claim, claim 60, has been rejected, along with dependent claims 62-64, 67 and 69-73, under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No.

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5,147,341 to Starke et al. ("Starke"). The Examiner also rejected claim 68 under 35 U.S.C. 103(a) as being unpatentable over Starke in view of U.S. Publication No. 2004/0158231 to Tanghoj et al. or in view of U.S. Publication No. 2004/0153051 to Israelsson et al.

As clarified in amended claim 60, the present invention is directed to a catheter assembly that includes a urinary catheter having a proximal end adapted for insertion into a urinary canal and an opposite distal end, and a catheter package having a hose with a cavity for accommodation of the catheter. The proximal end of the package has a catheter outlet adapted to dismantle or dispense the proximal end of the catheter from the catheter package. The package is also provided, *at an opposite distal end thereof*, with a separate opening. This separate opening is closed by a *closing structure that is connected to the catheter* for causing the package to be *opened* upon removal of the catheter from the package *prior to use thereof*. This is not shown or suggested by the prior art.

Starke discloses a self-contained catheter assembly in which the insertable end of the catheter passes through an introducer assembly 14, which may be said to dismantle or dispense the insertable end from the receptacle 11 for use. At the opposite end of the catheter, i.e., that end that remains

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within the receptacle 11, the catheter is provided with an enlarged arresting member 22 which prevents or "arrests" extraction of the catheter from the container, the member being unable to pass through the narrow opening defined by the introducer assembly 14. There is, in Starke, no opening in the receptacle or package that is *separate from the catheter outlet*. Nor is there any structure *connected to the catheter* that, upon removal of the catheter from the package prior to use, serves to open the *separate opening in the package*, as claimed by the present invention.

In the Examiner's discussion of Starke as applied to claim 60 in the Detailed Action, Starke is stated as teaching a catheter and a catheter package, the package having in a proximal end a catheter outlet adapted to dismantle the proximal end of the catheter from the catheter package. Applicants understand the package to be receptacle 11 and the catheter outlet to correspond with the opening 18 within which the introducer assembly 14 is mounted in the receptacle. The catheter tube is made to project through the assembly 14 prior to insertion by the user.

The Examiner then states that Starke teaches "a sealing structure to provide a substantially liquid tight seal between

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the catheter package and the urinary catheter while the catheter is being dismantled." This limitation is not part of claim 60.

Instead claim 60 further sets forth a closing structure that is connected to the catheter and which closes an opening in the *distal end* of the *catheter package*. This closing structure causes the package to be opened when the catheter is removed or made to project from the package prior to use. This is not shown by Starke.

In an effort to address what the Examiner may have intended, in Starke the introducer assembly 14 includes a mounting member 40 that has proximal and distal ends from which the catheter tube 21 extends. The drainage end of the tube 21, which extends from the distal end of the mounting member 40, has the enlarged arresting member 22 thereon to prevent complete removal of the tube from the receptacle 11 during ordinary use. Once the user has inserted the catheter for use, urine flows into the receptacle through the tube 21 and arresting member 22. Thus, the arresting member 22 is always open and does not ever serve to "close" the distal end of the mounting member 40. This is further substantiated by the identification of the arresting member 22 as being a "conventional syringe connection" (col 3, lines 5-7), which would absolutely be open; therefore, the opening in the distal end of the mounting member 40 is never

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closed and the arresting member cannot be considered to be a closing structure as is claimed by the present invention in claim 60.

Claim 60 is therefore not anticipated by Starke nor is it suggested thereby. Instead of a package that is opened at the distal end when the catheter is removed from the package for use, Starke teaches that the receptacle 11 forms a closed fluid collection chamber 20 into which urine is drained (see column 2, lines 56-68). Clearly, projecting of the catheter from the receptacle for use does not open the distal end of the receptacle; rather, the receptacle or package provides a self-contained urine drainage and storage unit which can be disposed of, along with the urine collected therein and the catheter, when the user is done (see column 5, lines 25-35). This is not at all what is set forth in claim 60.

For at least the foregoing reasons, claim 60 is patentable over the prior art. Favorable reconsideration and allowance thereof is requested. Claims 61-73 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein, including additional species that incorporate all the limitations of the allowable generic claim 60.

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The Examiner provisionally rejected claims 1, 3, 4, 7, 16, 21-23, 26-29, 32-34, 60, 62-64, 67 and 70-72 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20 of co-pending patent application, Serial No. 10/482,229, and as that of claims 1-87 of co-pending patent application, Serial No. 10/183,984, both co-pending applications being to Tanghoj et al. ("the Tanghoj applications"). In that the rejection is provisional, the conflicting claims in the Tanghoj applications not having been patented, and the currently pending claims being otherwise in condition for allowance, Applicants request withdrawal of this provisional rejection as the only remaining issue, and allowance of the present application.

Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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